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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,892	06/06/2001	Gavriel Meron	P-1800-US	7467

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 12/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,892

Applicant(s)

MERON ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24-53 is/are pending in the application.
- 4a) Of the above claim(s) 16-22 and 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Copy of approved drawing corrections.

FINAL ACTION

Response to Arguments

1. Applicant's arguments filed on 9/25/03 have been fully considered but they are not persuasive. The amended claims merely cite the sensed parameters which were previously addressed under paragraph 20 of the last Office Action. As such the claims are amended to correspond to the added limitation, as such, new grounds of rejection exist. The Examiner approved the drawing corrections.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-12, 24-28, 30-39, 41-43 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schentag et al.'607, of record in view of Lemelson'378, of record.

Schentag et al.'607, teaches a method of delivering a sensing and utility device to a target location in the gastrointestinal tract comprising the steps of:

generating a map of the gastrointestinal tract employing a sensing and utility device for a first pass through the gastrointestinal tract (col. 3, lines 9-62; referring to the capsule sensing the location in the alimentary canal and having the utility of transmitting signals regarding its location as well as delivering medicaments, wherein the capsule is typically used in a first pass

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exploratory procedure for mapping the gastrointestinal tract (see in particular col. 3, lines 46-53)); and

delivering said sensing and utility device to a target location identified on said map using said sensing and delivering device in a second pass (col. 3, lines 53-58).

Schentag et al.'607 teach a sensing and utility device for performing a job at a target location in a gastrointestinal tract comprising:

sensing means for generating data in a first and second pass through the gastrointestinal tract (col. 3, lines 4-53; col. 4, lines 21-68 and col. 5, lines 1-18; referring to the radio signal transmitter, which generates data to create a precise map during a first pass (see especially col. 3, lines 28-33 and col. 3, lines 46-53) and subsequently generating data in a second or more passes and comparing that data with the first pass generated map (see col. 3, lines 34-42));

means for signal analysis of the data generated in the first and the second pass (col. 3, lines 18-22 and col. 5, lines 10-18; referring to the comparator/computer means 12 for analysis of the transmitted signal during subsequent passes, including a second pass, with the first pass generated map to determine the current location of the capsule);

means for performing a job in the gastrointestinal tract (col. 5, lines 19-26; referring to medicament releasing assembly causing release of the medicament, from the medicament storage compartment at a location of interest); and

means for controlling the sensing and utility device and the means for performing a job, operable according to said signal analysis (col. 5, lines 3-26; referring to the central processing unit 9 for receiving the transmitted positional signals, analyzing them and triggering treatment at the appropriate location of interest).

Schentag et al.'607 teach inserting the sensing and utility device into the gastrointestinal tract (col. 3, lines 9-10; referring to the ingestion of the capsule in the gastrointestinal or alimentary canal); locating said sensing and utility device (col. 3, lines 18-41 and col. 5, lines 10-18); and displaying the location on a position monitor (col. 5, lines 14-18).

Schentag et al.'607 teach displaying the location of the device two or three dimensionally (col. 3, lines 28-41 and col. 5, lines 14-18; referring to mapping of the gastrointestinal tract via first pass and subsequently locating the device in other passes and providing a visual confirmation of its location on a monitor, inherently providing at least a two dimensional image of the gastrointestinal tract by providing the map and the location of the device).

Schentag et al.'607 teach inserting the sensing and utility device into the gastrointestinal tract (col. 3, lines 9-10; referring to the ingestion of the capsule in the gastrointestinal or alimentary canal); receiving data from said sensing and utility device (col. 3, lines 14-18); performing signal analysis of the data generated in the first pass and of the data generated on the second pass (col. 3, lines 28-33 and col. 3, lines 46-53; referring to generating data to create a precise map during a first pass and subsequently generating data in a second or more passes and comparing that data with the first pass generated map (see col. 3, lines 34-42)); and controlling the sensing and utility device according to said signal analysis (col. 5, lines 3-26; referring to the central processing unit 9 for receiving the transmitted positional signals, analyzing them and triggering treatment at the appropriate location of interest).

Schentag et al.'607 teaches that the first pass and the second pass are one or more passes (col. 3, lines 34-42; referring to first mapped route being compared with subsequent plural passes).

Schentag et al.'607 teach that the target location is a location of a pathology (col. 3, lines 53-58; referring to the controlled release of a medicament at a desired site, it is inherent that the desired site is a location of a pathology, otherwise no medicament treatment would be required).

Schentag et al.'607 teach means for performing a job in the gastrointestinal tract that are selected from means for releasing substances into the gastrointestinal tract and means for collecting substances from the gastrointestinal tract (col. 3, lines 53-62 and col. 5, lines 19-26; referring to the means for releasing substances into the gastrointestinal tract).

Schentag et al.'607 teach the use of a capsule or the use of multiple capsules in different passes (col. 3, lines 29-42). It is inherent that either a single or an additional capsule is used in different passes having all the limitations as stated above.

Schentag et al.'607 teach all the features of the instant invention including a first and second pass as described above for mapping the gastrointestinal tract, except for a sensing means sensing parameters of the gastrointestinal tract wherein the means for signal analysis analyze the sensed parameters and controlling the capsule based on the analysis. In the same field of endeavors, Lemelson'378 teaches a sensing means to sense parameters of the gastrointestinal tract and wherein the means for signal analysis analyze the sensed parameters (col. 2, lines 1-6; col. 9, lines 29-67; col. 10, lines 1-16; col. 11, lines 1-5; col. 20, lines 53-67 and col. 21, lines 1-7; referring to the swallowing capsule having sensors for detecting physiological parameters of the gastrointestinal tract and transmitting to a shortwave receiver located exterior to the body, having a computer processing and analyzing the transmitted information) and wherein the control of the capsule depends on the analysis of the parameters (col. 21, lines 14-62; referring to treatment based on the analysis).

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It would have been obvious to one skilled in the art at the time that the invention was made to have modified Schentag et al.'607 to incorporate the sensing means, transmission of the sensed information, and analysis of such information by a computer, with responsive treatment as taught by Lemelson'378 in order to not only map but to also localize the area of interest in order to treat. Diagnosing with multiple sensors for a variety of possible diseases in the environment of interest and in essence, allowing for real-time analysis of the collected information allowing for responsive treatment based on the analysis, provides an improved diagnosis and treatment tool as taught by Lemelson'378 (motivation for combining all features is described in col. 2, lines 1-46 of Lemelson'378; describing the improved capabilities for diagnosis and treatment provided by sensors and analysis of the sensed information to effectuate treatment).

4. Claims 4-5, 29, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schentag et al.'607, in view of Lemelson'378, of record and further in view of Iddan et al.'531, of record.

Schentag et al.'607 in view of Lemelson'378 teach all the features of the instant invention including a first and second pass as described above for mapping the gastrointestinal tract, except for displaying of the device two or three-dimensionally and as an overlay to a schematic presentation. In the same field of endeavor, Iddan et al.'531 teach displaying of the device two or three-dimensionally and as an overlay to a schematic presentation (col. 5, lines 7-16 and col. 6, lines 7-11). It would have been obvious to one skilled in the art at the time that the invention was made to have incorporated and used the system as described in Iddan et al.'531 in the system of Schentag et al.'607 in view of Lemelson'378, via use of a camera (see Iddan et

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al.'531, col. 1, lines 55-61, col. 5, lines 7-16, and col. 6, lines 7-11) in order to get a better diagnostic tool of the area of interest via viewing a video of the area of interest as well as its location over a schematic in a two- or three- dimensional display. The user would be able to better verify the area of interest prior to treatment with medicament.

5. Claims 13-15 are rejected under 35 U.S.C. 103(a) as obvious over Iddan et al.'531 in view of Lemelson'378, of record.

Regarding claim 13, Iddan et al.'531 teach a system for delivering a sensing and utility device to a target location in the gastrointestinal tract comprising:

a sensing and utility device consisting of:

a camera system (element 24 of Figure 2 and col. 3, lines 27-34; referring to the CCD camera system);

an optical system for sensing an area of interest onto said camera system (element 26 of Figure 2 and col. 3, lines 33-34; referring to the optical system focusing the images onto the CCD camera);

a transmitter which transmits video output of said camera system (element 28 of Figure 2 and col. 3, lines 34-35; referring to the transmitter which transmits the video signal of the CCD camera);

means for performing a job in the gastrointestinal tract (col. 3, lines 38-40; referring to sensor elements for detecting physiological conditions in the gastrointestinal tract such as pH, temperature and pressure);

a reception system which receives said transmitted video output, said reception system comprising:

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an antenna array capable of surrounding the body and comprising a plurality of antennas for receiving said transmitted video output and for producing a plurality of received signals (col. 1, lines 62-66; also see col. 4, lines 27-67; and see Figure 4 antenna array 40);

a demodulator capable of transforming said plurality of received video signals into a single video stream (col. 1, line 67 and col. 2, lines 1-2); and

a data processing system which generates tracking and video data from said single data stream (data processor 14 as described in col. 5, lines 19-67 and col. 6, lines 1-11).

Iddan et al.'531 teach an analyzing unit for signal analysis of the video output. Iddan et al.'531 teach an analysis by which there is recognition of the location of interest in present and past movements of the capsule through the gastrointestinal tract (col. 5, lines 7-16 and col. 5, lines 56-67 and col. 6, lines 1-8).

However, Iddan et al.'531 do not teach an analyzing unit for controlling the sensing and utility device. In the same field of endeavor, Lemelson'378, teaches an analyzing unit for signal analysis and controlling the capsule such as medically treating the area of interest (col. 21, lines 63-67 and col. 22, lines 1-14) as well as use of a video camera (col. 22, lines 53-67).

It would have been obvious to one skilled in the art at the time that the invention was made to have incorporated the controlling aspect of Lemelson'378 to control the capsule of Iddan et al.'531 in order to remotely activate treating the diseased area of interest, such as via medicament release, once the area of interest has been localized or identified via the analyzing unit.

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Regarding claims 14 and 15, Iddan et al.'531 teach a sensing and utility device which is swallowable and which is placeable in the gastrointestinal tract (col. 3, lines 13-17).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Crowley et al.'418 teach a portable tissue spectroscopy apparatus and method.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

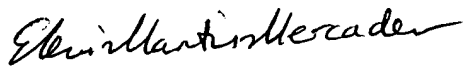
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM